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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61F 2/44 — A1

(11) International Publication Number: WO 98/58604

(43) International Publication Date: 30 December 1998 (30.12.98)

(21) International Application Number: PCT/GR98/00017

(22) International Filing Date: 17 June 1998 (17.06.98)

(30) Priority Data:
970100248 20 June 1997 (20.06.97) GR

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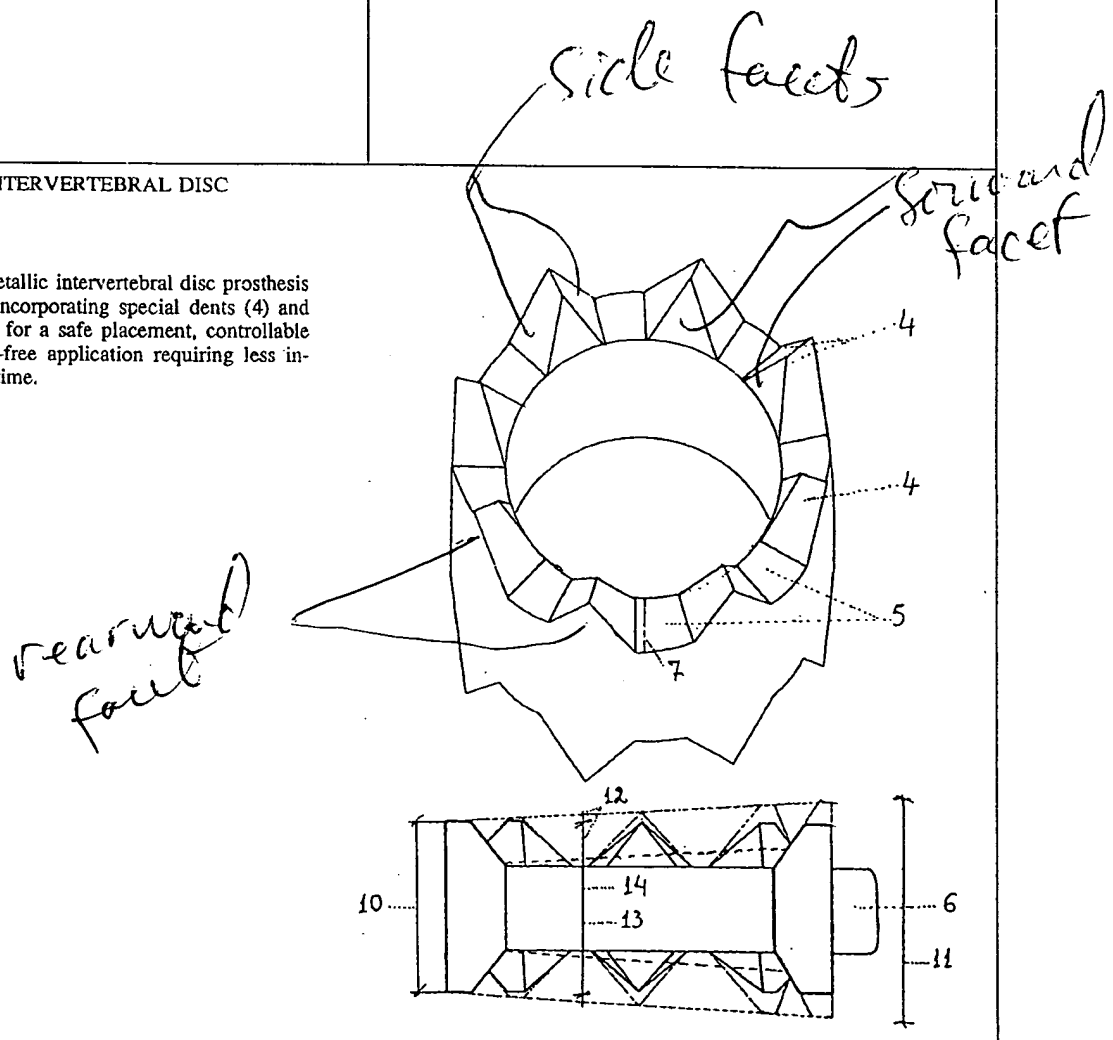
(81) Designated States: US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: METALLIC INTERVERTEBRAL DISC

(57) Abstract

A simple and safe metallic intervertebral disc prosthesis (3a) of the cervical spine incorporating special dents (4) and sitting positions (stops) (5) for a safe placement, controllable penetration, and migration-free application requiring less instrumentation and surgical time.



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D E S C R I P T I O N

Title: Metallic intervertebral disc

Technical field:

A metallic dentate ring prosthesis, (Figures 1,2) filling the gap between two cervical vertebrae, after removal of the intervertebral disc, for use in surgical decompression and fusion-stabilization of the cervical spine.

Vertebral body=1, vertebral laminae=2, normal intervertebral disc=3, substitute intervertebral disc-prosthesis=3a

Ring, substitute, prosthesis, implant, are terms to be used.

Evaluation of the existing relative status of knowledge

Their main purpose after filling the gap between two cervical vertebrae following the removal of the intervertebral disc is to correct and maintain an adequate intervertebral space in order to allow the spinal roots to course freely through the intervertebral foramina. One other important purpose is to stabilize the vertebral column immobilizing the joint between the vertebral bodies and to encourage osteogenesis. Some of other prostheses allow unrestricted motion in use in the replacement of spinal discs segments.

The prostheses in use today come in different shapes, dimensions and finishing. Two main characteristics are that the thickness of their ring is less than 1mm. and that other prostheses have ring and edges of the ring with the same thickness thus allowing the edges to penetrate the vertebral bodies. This results to loss of height of the intervertebral space and to compression of the spinal roots which run through the adjacent intervertebral foramina.

The application of loading shearing forces in some prostheses with many dents - serrated structure, i.e. more than 15 up to 20 dents, may act as the function of the saw namely as the saw is sawing the wood, resulting in destroying the in-between the dents holding osseous mass, which can lead to loosening of the stable positioning of the implant.

Other used prostheses without dents, although they have built-in mechanism to maintain the height of the intervertebral space, however they carry the risk of

migration, and they cannot be applied securely in more than one invertebral spaces without further stalilization techniques with plates and screws. Moreover this additional procedure increases considerably the surgical time and the risk of contamination.

Other artificial discs consisting of two components but being mobile (moveable) they allow unrestricted rotational and flexion-extension bending motion in the spinal disc segments they replace, thus, their function is exactly the opposite of what is needed in fusion-stabilization spine procedures.

In addition, those of the existing metallic rings without dents require major instrumentation, time consuming insertion techniques and additional stabilization materials (plates and screws) in cases of insertion of prosthesis in more than two intervertebral spaces.

The advantages of our prosthesis are:

a) Because of the special dents, it is stabilized in situ securely minimizing the risk of migration to any direction.

b) Encourages osteogenesis in the inner opening of the ring.

c) Maintains adequate intervertebral height due to its special stops between the dents controlling, thus, absolutely the degree of the impaction and the height of the intervertebral space preserving a quite enough holding osseous mass. in-between the dents.

d) Because the thickness of the ring-cylinder and the thickness of the dents is different, the implant is secured between the vertebrae preventing the penetration furthermore into the vertebral body and the subsequent loss of the intervertebral space height with all its related consequences.

e) Because of its special design it penetrates only at a controllable predetermined depth and succeeds in preventing further penetration.

f) Requires much less instrumentation and surgical time for insertion, minimizing thus, the risk of contamination.

Obviously, even in cases where two or more prostheses are used there is no need for further stabilization with plates and screws.

REVEALING THE INVENTION

Metallic intervertebral disc (3a) with an outer periphery less than the periphery of the vertebral body so that the prosthesis interposes in-between the cervical vertebral bodies after removal of the intervertebral disc (Figure 2)

This prosthesis is a cylinder with the same thickness all over, parallel or trapezium (in profile). Its periphery could be circle or elliptic (oval) (Figures 4,5)

This metallic intervertebral disc (3a) in its upper and lower surface and all round the cylinder finishes with dents (4) and footsteps (5) stops (sitting positions) (Figures 2, 4, 5).

This metallic intervertebral disc in one part of the outer periphery of the cylinder (this part then is the anterior part of the prosthesis) finishes in a holder (6) which facilitates the positioning of the metallic disc during its application in-between the two vertebral bodies (Figures 4, 5), viewed from below, view, A-A section). In the trapezoid prosthesis the holder (6) is the anterior (the higher - 7,5mm) part of the outer periphery of the cylinder [Figures 4, 5, .A-A section].

The thickness (7) of the ring of the prosthesis is 2mm, the external (8) ring diameter 14mm and the internal (9) ring diameter 10mm. The height of the prosthesis (dents included) parallel (10) or trapezium (11)] is 6mm to 7,5mm. Dent height (12) is 1,5mm - 2mm. The height of the prosthesis without the dents is 3mm - 4,5mm [(parallel (13) or trapezium (14)]. (Figures 4, 5).

The declivity or slope of the dent (15) is 2mm - 3mm, the distance edge dent length - ring (16) is 1,5mm or 2mm. The thickness of the dent at the edge dent (which edge is sharp)- edge dent length (17) is 1mm and the internal dent angle (18) is 45^0 - 90^0

The thickness of each dent gets progressively less going upwards i.e. from 2mm at the base of the dent- thickness of the ring - cylinder (7) to 1mm at the edge dent - edge dent length (17).

The dent gets thinner - narrow- at its edge, at the expense of its inner side (part), preserving its outer side (part) at the same vertical level with the outer periphery of the ring - cylinder. (Figures 4, 5, 6).

In relation to the level of the cervical spine where the prosthesis will be used, the number of the dents will vary accordingly, usually 8 or less all round the upper and lower surface of the cylinder. (Figures 4, 5).

It is obvious (because of the normal lordosis of the cervical spine when it is preserved) that in the case of the trapezoid prosthesis the higher dents (2mm) and therefore the higher part of the cylinder (7.5mm), when applied in-between the bodies of the vertebral bodies, have to be positioned on the anterior part of the intervertebral space. Thus, the anatomy and the function of the spine (cervical in particular) is maintained even more.

The shape of the holder (6) is a small cylinder with horizontal the anterior surface and concave the posterior surface where it continues transitioned into the (principal) cylinder of the prosthesis. The distance, where the horizontal surface of the holder (anterior surface) changes having a perpendicular course to the cylinder of the prosthesis, is 2mm (i.e. thickness of the holder sideways).

The holder (6) of the prosthesis is shaped in such a manner to hold the prosthesis with safety and to easily remove it, if the prosthesis is not applied correctly.

Thus, our intervertebral disc has the following characteristics:

1. It restores the height of the intervertebral space back to normal (i.e. to 1/3 of the vertebral body).
2. It has α. such dents (4) to inhibit the migration of the artificial disc β. in-between the dents has sitting positions (stops) (5) which inhibit the impaction of the artificial disc and c.it has an internal opening which is filled with autologous osseous implant so that a bony bridge (osteogenesis) takes places between the upper and lower lying vertebrae.
3. It has different thickness cylinder (ring) and dents to avoid further penetration into the adjacent vertebrae.
4. It stabilizes the joint between the vertebrae immediately from the first postoperative day and secondary the bony bridge takes place after 6 months time.

This prosthesis differs from the others because its dents succeed one each other in such a manner so that the existence of a stop (like footstep) in-between the dents inhibits the complete impaction of the prosthesis in the vertebral bodies. It is nature,

the structure and the shape of the special dents (4) (like stegosaurus back) (Figure 3) combined with the in- between stops (5) and the difference in thickness between cylinder -ring (7) and dents (17), (Figures 5, 6) which account not only for a better impaction but also for a more secure application and a better holding of this prosthesis after the removal of the intervertebral disc.

The better impaction of this prosthesis is achieved because of the dents whose special shape getting progressively narrow upwards (edge dent length) and having a proper finishing, (sharp edge), which is not like a needle, pierce into the vertebral bodies without penetrating the bodies circumferentially.

The secure application and better holding of this prosthesis is due to the in-between the dents stops, which inhibit the prosthesis to get further impacted, so that in combination with the dents and the succession dents - stops with the special characteristics they possess (shape and dimensions) they do not allow the migration of the prosthesis.

Additionally, the different thickness between cylinder (ring=2mm) and dents (1mm) accounts for preventing further penetration into the vertebrae.

Because of its special design (Figures 4, 5) this prosthesis succeeds in both the following purposes: α. to penetrate controllably predetermined up to the point we desire, into the adjacent upper and lower terminal plates of the vertebral bodies and β. to stop to a secure point in the vertebral bodies which is not the case with other prostheses.

This prosthesis secures from migration more than any other prosthesis.

It does not require built-in mechanism for proper placement, on the other hand only a limited number of instruments are required for its application constituting its insertion technique very simple.

Obviously, even in cases with more than two prostheses applied i.e. in two or more cervical intervertebral spaces there is no need for further stabilization with plates and screws.

To obtain experience in applying this prosthesis is easy, takes less time of training and can be easily achieved by neurosurgeons or orthopaedic surgeons, assuring a good final result.

This invention is compatible with less invasive surgical techniques:

Its cost combined with the cost of its application is low because:

1. It is simple in construction
2. There is no need of any special application instrument
3. Its use avoids the additional placement of stabilizing -fusion plates and screws in cases of multiple prostheses.
4. The method of positioning the prosthesis is less tiring for the surgeon and the whole procedure is more functional for the patient.

Example of an application of this invention

Male 46 years suffers from intractable pain radiating to the right arm for six months after a car accident. Clinically motor power diminished in the segments served by the cervical roots C_5,C_6. The neurophysiological and neuroradiological investigation in combination with the clinical examination revealed a C_5,C_6 (cervical) intervertebral disc prolapse compressing severely the relevant roots.

The patient in order to be cured must have an operation. This operation consists of a cervical discectomy that is removal of the diseased prolapsed intervertebral disc at the level C_5,C_6 which compresses the neural elements. However, after the removal of the intervertebral disc the height of the intervertebral space diminishes and this may result in roots compression.

To avoid this situation the intervertebral space must be filled. Thus, the metallic intervertebral disc interposes in-between the two vertebral bodies restores the anatomy of the area keeping the adjacent neural elements free and leaving undisturbed the course of the roots. A major problem which can occur after the application of the prosthesis is the migration of the prosthesis.

It is because of the special dents (and, in certain number 8 or less) and the sitting positions (stops) succeeding one each other and having this special shape and dimensions, in addition to the difference in thickness between ring (cylinder) and dents that this metallic intervertebral disc holds its position stable once fitted and cannot migrate after its positioning.

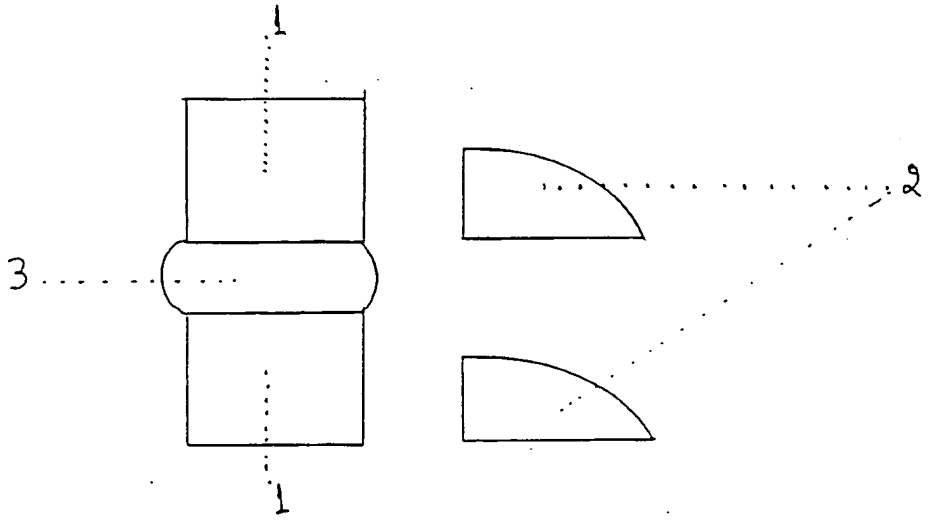
Specifically, it is emphasized that in our prosthesis the internal bigger (wider) opening (compared to the opening of other prostheses which is smaller) helps more in osteogenesis and therefore accelerates the production of the bony bridge (which is in our case bigger in volume) between the two bodies.

CLAIMS

1. Metallic intervertebral disc which consists of one single piece (element) of a metallic (titanium alloy) ring (cylinder) with an outer periphery less than the periphery of the vertebral body so that the prosthesis interposes in-between the cervical vertebral bodies after removal of the intervertebral disc. In the touching points, that is where the substitute touches the vertebral bodies, that is on the upper and on the lower surface and all round the ring (cylinder) of the substitute must be dents (similar in shape) with such certain length and finishing (the dents) to penetrate upwards and downwords into the vertebral bodies steadily and to avoid migration. The number of the dents can vary according to the level where the implant will be placed, usually around 8 or less in each upper and lower surface of the implant. In-between the dents must be interposed sitting positions (stops) which will inhibit the further impaction of the prosthesis into the vertebral bodies so that the desired height of the intervertebral space is maintained. The holding osseous mass between two consecutive dents to be such -quite enough- to avoid the phenomenon of the functions of the saw that may occur in loading shearing forces. The whole invention - design to be such to penetrate only into a controllable predetermined depth to succeed in preventing further penetration.
2. Metallic intervertebral disc as it is referred to claim 1 which the thickness (width) of the ring (cylinder) to be 2mm and the thickness of the dent at the edge dent (edge dent length) to be 1mm thus, the prosthesis having cylinder and dents with different thickness (width), copes with increased loading shearing forces preventing the implant to penetrate further more into the vertebral body avoiding any subsequent loss of the intervertebral space height once the implant is initially placed in-between the vertebrae.
3. Metallic inervertebral disc as it is referred to claims 1 and 2, which the height without the dents, to be such long as the height of the normal intervertebral disc.
4. Metallic intervertebral disc as it is referred to claims 1 to3, which must have an internal opening so that the bony bridge between the bodies of the upper and lower vertebral, takes place.

5. Metallic intervertebral disc as it is referred to claims 1 to 4, which can be a cylinder with the same thickness all over, parallel or trapezium (inprofile). Its periphery could be circle of elliptic (oval).
6. Metallic intervertebral disc as it is referred to claims 1 to 5, which the height can be more than the height of the intervertebral disc to cover cases of partial replacement of the underlying or the overlying vertebral bodies.

Figure 1



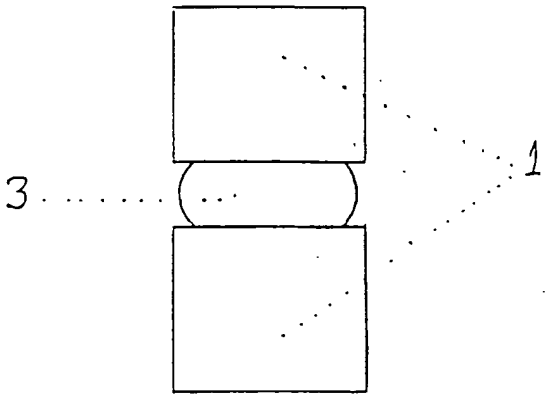
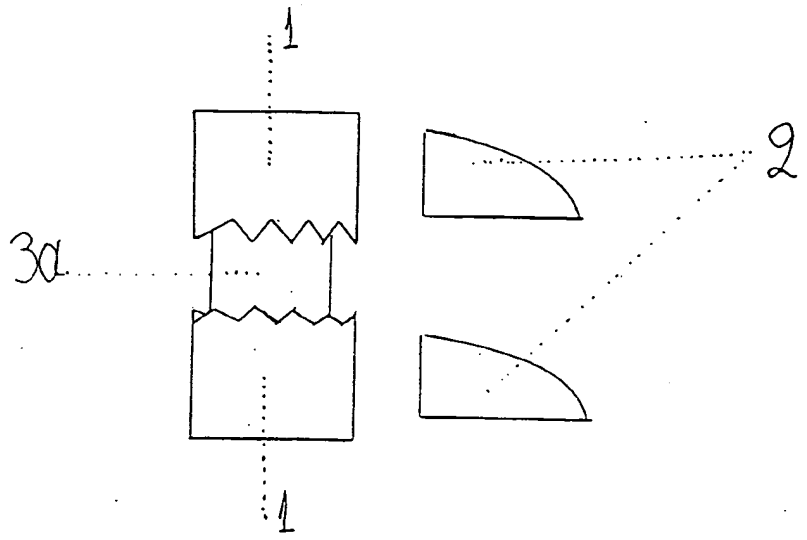


Figure 2



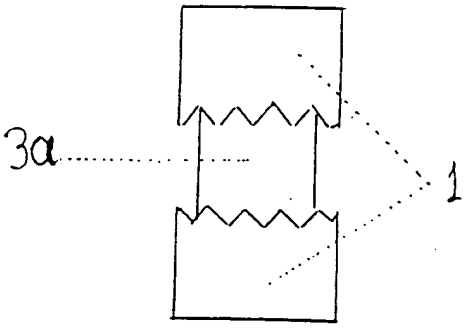


Figure 3

"STEGOSAURUS"

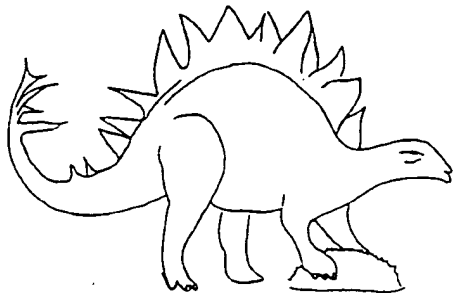


Figure 4

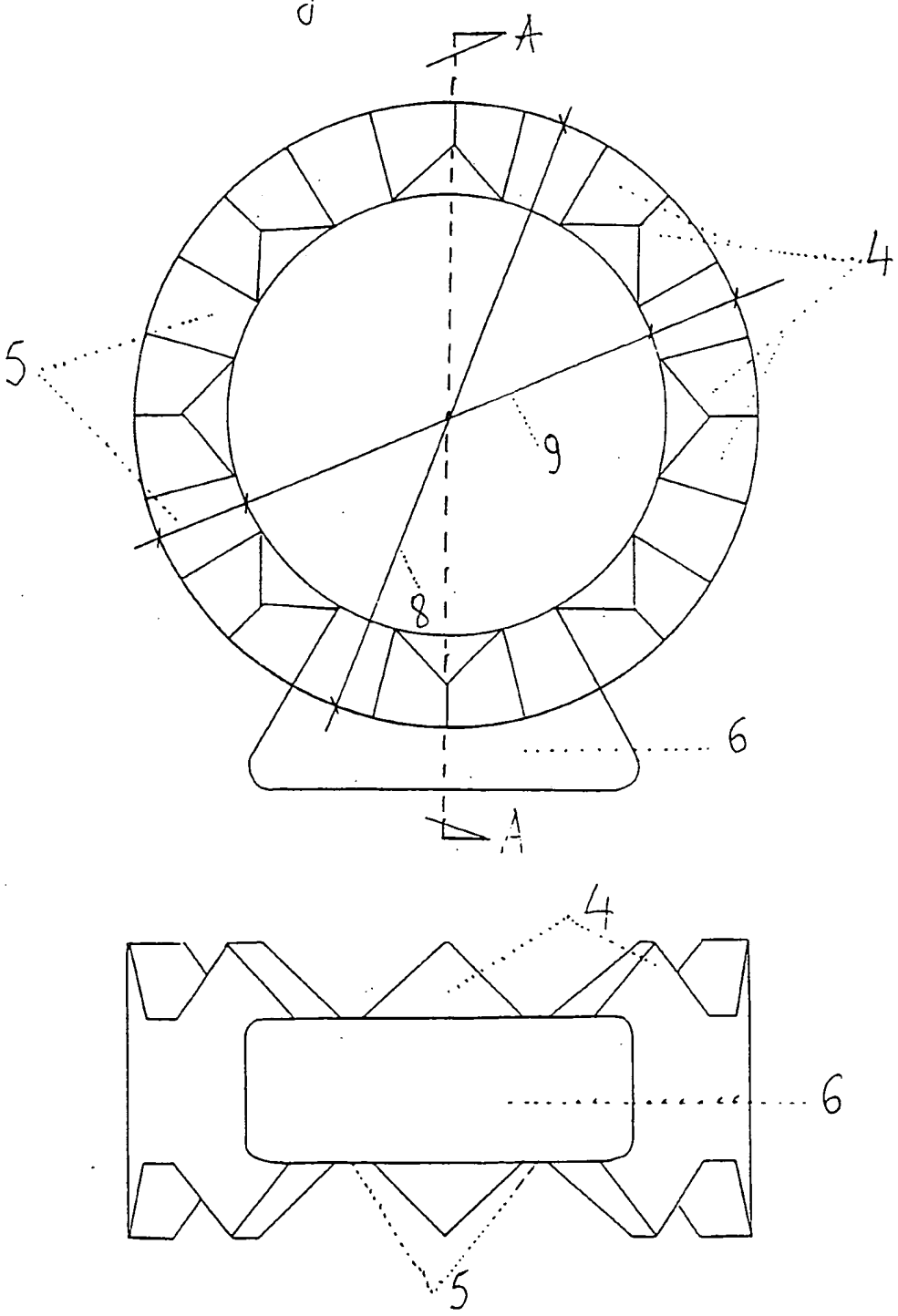


Figure 5

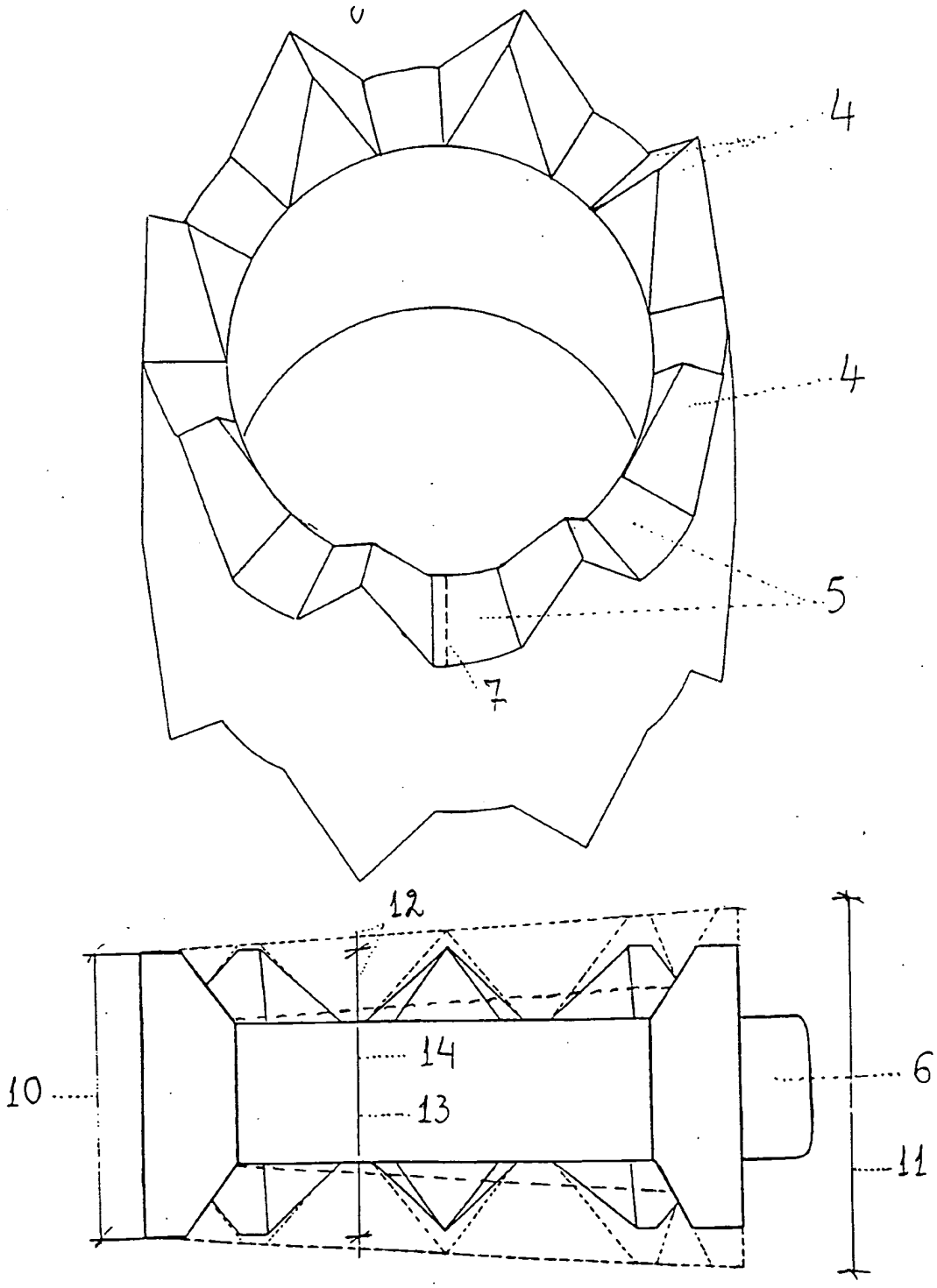
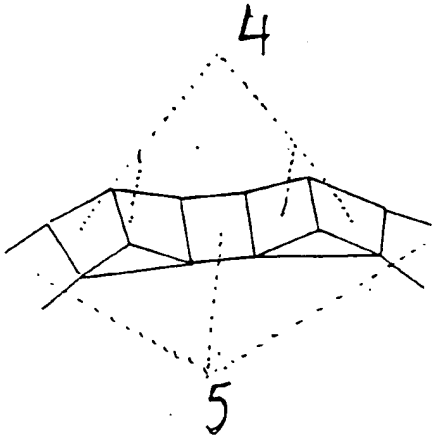
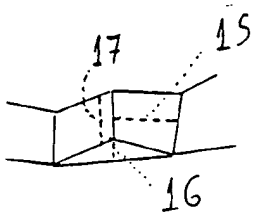


Figure 6





INTERNATIONAL SEARCH REPORT

International Application No
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A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/44

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR 2 724 312 A (ALBY) 15 March 1996 see abstract; figures 1,3,5	1-5
Y	FR 2 733 413 A (JBS) 31 October 1996 see abstract; figures 1-3	1-6
Y	WO 96 40014 A (DANEK MEDICAL) 19 December 1996 see abstract; figures 2,3,8,11	1-6
A	FR 2 703 580 A (ROBERT) 14 October 1994 see abstract; figure 1	1-5
A	US 5 192 327 A (BRANTIGAN) 9 March 1993 see the whole document	6
A	DE 195 19 101 A (HARMS) 28 November 1996 see abstract; figures	6
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19 October 1998	27/10/1998

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P,X	WO 97 32547 A (THALGOTT) 12 September 1997 see the whole document	1-5

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Information on patent family members

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